In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

BRENT LANGLEY,	*	
	*	No. 17-837V
Petitioner,	*	Special Master Christian J.
	*	Moran
	*	
v.	*	
	*	Filed: March 3, 2022
SECRETARY OF HEALTH	*	
AND HUMAN SERVICES,	*	entitlement, diagnosis,
	*	encephalopathy, cytokines
	*	
Respondent.	*	

Bridget McCullough, Muller Brazil, LLP, Dresher, PA for petitioner;
Jeremy Fugate, United States Dep't of Justice, Washington, DC, for respondent.

PUBLISHED DECISION DENYING ENTITLEMENT[1]

Seeking compensation in the Vaccine Program, Brent Langley alleges that a tetanus vaccine caused him to suffer an encephalopathy. The Secretary opposes this claim. Both parties developed their positions by filing a series of reports from experts and then advocated through briefs. Mr. Langley has not established with preponderant evidence that he suffered an encephalopathy. Because his claim for compensation rests upon this flawed premise, his claim is denied. In addition, even if Mr. Langley presented preponderant proof that he suffered from an encephalopathy, he has not presented persuasive evidence that a tetanus vaccine can be the cause-in-fact of an encephalopathy.

[1] The E-Government Act, 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services), requires that the Court post this decision on its website. Pursuant to Vaccine Rule 18(b), the parties have 14 days to file a motion proposing redaction of medical information or other information described in 42 U.S.C. § 300aa-12(d)(4). Any redactions ordered by the special master will appear in the document posted on the website.

I. Facts[2]

A. Before Vaccination

Mr. Langley was born in 1958. Exhibit 10 (affidavit) ¶ 1. He worked for Computer Technology Associates. Id. at 5.

On March 14, 2014, Mr. Langley presented to his primary care physician ("PCP") and reported that he had been suffering from headaches and fatigue, which were "sometimes associated w/ a sense of anxiety." Exhibit 11 at 65.

On April 16, 2014, Mr. Langley presented to his PCP and reported that he continued to have headaches and was experiencing intermittent diarrhea. Exhibit 11 at 62-63. Mr. Langley's PCP noted that stress was possibly affecting his gastrointestinal tract. Id.

Approximately two months later, on June 11, 2014, Mr. Langley reported to his PCP that he was not physically active in the winter, was physically stressed by heat and exertion, and that he would become lightheaded while outside in the heat. Exhibit 11 at 56-57.

B. Circumstances surrounding Vaccination

On August 1, 2014, Mr. Langley presented to Family Care of Dillsburg for a cat bite on his fourth right finger that had occurred the night prior. Exhibit 11 at 53. Mr. Langley reported that the cat appeared to be very sick and had died shortly after biting him. Id. Dr. Uniacke referred him to a local emergency room for a rabies vaccination.

In the emergency room, Mr. Langley exhibited full range of motion in the finger and no proximal streaking. Exhibit 13 at 27. Mr. Langley was started on immunoglobulin and given rabies and a tetanus vaccine.[3] Id. at 23, 27-28. Mr. Langley's claim in Vaccine Program is based upon the tetanus portion.

---

[2] The parties largely agree about the events in Mr. Langley's health that are relevant for determining whether the vaccination harmed him. Thus, this decision draws from the parties' briefs.

[3] At one place, the medical record indicates that Mr. Langley received a tetanus-diphtheria-acellular pertussis ("Tdap") vaccine. But, at a difference place, the medical record references a tetanus-diphtheria vaccine. The parties have not argued that the specific type of tetanus vaccine affects the outcome. For example, Mr. Langley has not asserted an on-Table claim that the acellular pertussis vaccine caused an encephalopathy. Nonetheless, the

C. Medical Records from Vaccination through December 2014

On August 21, 2014, Mr. Langley presented to Family Care of Dillsburg for anxious and fearful thoughts, depressed mood, difficulty concentrating, diminished interest or pleasure, excessive worry, and headaches. Exhibit 11 at 48-52. Mr. Langley reported that his symptoms of anxiety began two – three weeks prior, after he received immunoglobulin and a rabies vaccine. Id. at 48.[4] Mr. Langley reported difficulty concentrating at work and occasional short-term memory loss, in addition to muscle tension in his shoulders and upper extremities, trembling in his arms and hands, and pressure around his eyes and forehead. Id. The cat that bit Mr. Langley was cleared of rabies, so Mr. Langley's course of treatment for rabies exposure had been discontinued. Id. The PCP diagnosed Mr. Langley with an adjustment disorder with mixed anxiety and depressed mood. Id. at 51.

On August 30, 2014, Mr. Langley presented to the ER. Exhibit 13 at 11. The triage notes report he received the rabies series about a month ago and "since then has started with 'cognitive' issues." Exhibit 13 at 11. A computed tomography ("CT") scan of Mr. Langley's brain was performed, which showed "no acute intracranial process." Id. at 17. The ER physician noted "I have tried to reassure the patient that these symptoms [were] not due to the cat bite or the rabies vaccine." Id. at 10-11. Mr. Langley was discharged, noted to be driving himself, and was ordered to follow up with a neurologist. Id. at 12-13. Mr. Langley was instructed to use over-the-counter medications for the migraines and was started on Lexapro for anxiety. Id. at 10.

On September 5, 2014, Mr. Langley presented to Dr. Beverley Uniacke at Family Care of Dillsburg and reported waking up and experiencing trembling "all over" for thirty minutes, which then stopped suddenly, and was followed by a "rolling" sensation on the right side of his face and body followed by numbness in his right cheek and fullness in his right ear. Exhibit 11 at 44-45. In addition, Mr. Langley reported fatigue, generalized weakness, depression, anxiety, and paresthesias. Id. Dr. Uniacke explained that she could not say what exactly was causing these symptoms and that the information she "found on the immunoglobulin and vaccine said there weren't neurologic side effects." Id. at 46. She increased Mr. Langley's dosage of Lexapro. Id.

---

undersigned assumes that Mr. Langley received a Tdap vaccine because it encompasses a tetanus-diphtheria vaccine.

[4] This medical record does not mention the tetanus vaccine.

The appointment with a neurologist to whom Mr. Langley had been referred occurred on September 16, 2014, with Dr. Liana Laza at Pinnacle Health Neurological Surgery. Exhibit 12 at 8. Mr. Langley reported that he became sensitive to noise and light after receiving rabies and tetanus vaccinations on August 1, 2014. Id. Along with hypersensitivity, Mr. Langley complained of tremors, difficulty with memory and thinking, and muscle weakness. Id. On exam, Mr. Langley was normal except hyperreflexia on his left side. Id. at 10-11. Dr. Laza noted this case was "very unusual" and ordered a magnetic resonance imaging ("MRI") scan and an electrocardiogram ("EEG") to rule out demyelinating disease. Id. at 11. At the conclusion of the visit, Dr. Laza noted that Mr. Langley had "superimposed anxiety." Id.

Before those studies were conducted, Mr. Langley had an intervening appointment with Dr. Uniacke on September 19, 2014. Mr. Langley reported that he was sleeping all day and all night, occasionally felt anxious, and often felt trembling. Id. at 41. Dr. Uniacke's assessment was anxiety and cognitive changes. Id. at 43. Dr. Uniacke decreased Mr. Langley's dose of lorazepam and instructed him to follow-up with his neurologist. Id. at 43.

The MRI that Dr. Laza ordered took place later on September 19, 2014. The interpreting radiologist observed minor white matter lesions. Exhibit 12 at 14. Differential diagnoses included demyelinating processes, vasculitis, and lacunar infarction. Id. An EEG on October 6, 2014 was interpreted as normal. Exhibit 12 at 4.

Mr. Langley sought assistance from a specialist in infectious diseases, Lisa Tkatch, on October 6, 2014. Exhibit 16 at 6-8. Mr. Langley reported that on August 1, 2014, he received a rabies vaccination, rabies immunoglobulin, and a tetanus vaccination after a cat bit him on his right fourth finger. Id. at 6. That weekend, Mr. Langley reported that he developed a headache and felt poorly. Id. He subsequently developed issues with memory and thinking. Id. He described pressure around his head and felt as if he had a mask on. Id. at 6-7. Mr. Langley denied fever, coughing, shortness of breath, nausea, vomiting, or diarrhea. Id. at 7. A spinal tap (performed earlier on September 25, 2014) was normal; there was no evidence of rabies, toxoplasmosis or *Bartonella*. Id. Dr. Tkatch saw no evidence that an infection was causing Mr. Langley's symptoms. Id. Dr. Tkatch noted she felt "that most of his symptoms are related to a possible stress reaction from [the cat bite] incident." Id. at 8.

Mr. Langley returned to Dr. Uniacke on October 10, 2014. Exhibit 11 at 38-40. He reported problems with short-term memory loss, intermittent full body

tremors, and migraine headaches. Id. at 38. Dr. Uniacke diagnosed Mr. Langley with an adjustment disorder with mixed anxiety and depressed mood. Id. at 39. She started to taper Lexapro and recommended a follow-up visit with Dr. Laza. Id. at 40.

This return appointment happened on October 28, 2014. Exhibit 12 at 5-7. Mr. Langley reported that he was doing better, but still had some body tremors, mild headaches, and occasional dizziness. Id. at 5. Dr. Laza's assessment was that Mr. Langley's "entire complex of symptoms" were a reaction to the rabies vaccination. Id. at 7. Mr. Langley was instructed to follow-up in three (3) months. Id.

On November 13, 2014, Mr. Langley was seen by Dr. Uniacke for a preventative examination. Exhibit 11 at 33-37. Mr. Langley reported occasional lightheadedness and memory loss, but indicated that he would be returning to work full-time the following week. Id. at 33. The record's past medical history included neurologic side effects from rabies vaccine, "[g]radual resolution of most symptoms over 3 months." Id. Mr. Langley was instructed to continue to utilize the behavioral techniques for managing his anxiety. Id. at 37.

D. Medical Records from January 2015 through October 2017

On January 8, 2015, Mr. Langley presented to hematologist and oncologist Roy Williams, M.D., with a chief complaint of delirium and confusion. Exhibit 18 at 14. Dr. Williams obtained a lengthy history, which is more-or-less consistent with the information stated above. Dr. Williams stated that Mr. Langley's previous MRI was abnormal because it showed "foci of T2 bright signal involving white matter." Id. After an examination, Dr. Williams concluded Mr. Langley had an overwhelming systemic inflammatory process associated with widespread neuropathy. Assessments included central and peripheral neuropathy. Dr. Williams also opined that multiple concurrent vaccines clearly contributed to the onset of his disability. Id. at 15.

On January 13, 2015, Mr. Langley visited Joseph Annibali, M.D., a psychiatrist at the Amen clinic, for alternative treatment. Exhibit 2 at 1. Mr. Langley reported problems with memory, concentration, problem solving, and cognitive dysfunctions after adverse reactions to the rabies, tetanus, and immunoglobulin injections. Id. at 1. Mr. Langley also complained of headaches, confusion, and dizziness. Id. at 2. A single-photon emission computed tomography ("SPECT") scan was conducted and showed decreased activity in the prefrontal pole, temporal lobe, parietal lobe, and dorsal prefrontal cortex. Id. at 9.

Dr. Annibali's impression was that the "imaging shows a brain that is very unhealthy" and was hopeful a cause could be identified. Id. Dr. Annibali diagnosed Mr. Langley with encephalopathy, and disorder and dysfunction of the temporal and frontal lobes. Id. at 10. Dr. Annibali recommended various things, including hyperbaric oxygenation treatments, which Mr. Langley started on February 5, 2015.

Mr. Langley underwent a second MRI on January 27, 2015. This MRI showed that his brain activity was stable and that the white matter lesions were stable. Exhibit 15 at 115; exhibit 18 at 20.

On February 2, 2015, Dr. Roy Williams opined that Mr. Langley was unable to perform any of the functions required by his job given his diagnoses of encephalopathy, unspecified nonpsychotic mental disorder following organic brain damage, and encephalitis and encephalomyelitis following immunization procedures. Exhibit 4. Dr. Williams noted that Mr. Langley experienced "acute onset of disorientation, incoordination, memory loss, and an inability to concentrate associated with lethargy, fatigue, and emotional lability." Id. Mr. Langley's symptoms had resulted in dramatic deterioration of his mental, psychological, neurologic, and functional statuses. Id.

Starting February 2015, Mr. Langley saw Dr. Williams approximately monthly. See exhibit 18 at 26-79. He received hyperbaric oxygen treatments. See exhibit 17. During this period, Mr. Langley participated in "brain wellness/biofeedback treatment," but, according to one reviewer, reading the handwritten notes was "difficult." Exhibit 54-2 at 67.[5]

The insurance company providing disability benefits to Mr. Langley requested information to continue his eligibility on June 30, 2015 and August 10, 2015. Exhibit 18 at 87-88. Accordingly, Dr. Williams ordered another MRI during an August 13, 2015 office visit. Exhibit 18 at 89.

A few days later, on August 19, 2015, Mr. Langley had his third MRI, which showed mild small vessel ischemic changes but no interval change since his MRI on January 27, 2015. Exhibit 15 at 104; exhibit 18 at 89.

Mr. Langley's employer terminated his employment on September 15, 2015. Exhibit 47 at 271. Management needed people to perform duties that Mr. Langley

[5] The parties do not discuss this treatment in their briefs.

had been performing before he started his leave. Mr. Langley's supervisors expressed an interest in rehiring him if he could perform the duties of his job.

On November 23, 2015, Mr. Langley met with David Baker, Psy.D. Exhibit 54 at 250. Dr. Baker evaluated Mr. Langley and noted that his symptoms appear "stress related" and diagnosed Mr. Langley with an "adjustment disorder unspecified." Id.

The Pennsylvania Bureau of Disability Determination referred Mr. Langley to Dr. Ahmad Khan, an internal medicine specialist. Mr. Langley's chief complaints were: postimmunization encephalitis, memory loss, and migraine headaches. Exhibit 18 at 143. Mr. Langley provided a history beginning with the rabies vaccinations that he received after being bitten by a cat.[6] After examination, Dr. Khan's diagnoses included, among other conditions: (1) nonspecific diagnosis of postimmunization encephalitis, (2) common migraine headaches, and (3) memory loss. Id. at 145-46.

Mr. Langley had his first of a series of appointments with Claire Flaherty-Craig, Ph.D., a neuropsychologist at the Penn State Milton S. Hershey Medical Center, on April 6, 2016. Mr. Langley informed Ms. Flaherty-Craig about his rabies vaccines, immunoglobulin, and tetanus vaccination. Exhibit 15 at 67. On exam, Mr. Langley's scores were average for neuropsychological functioning; average to superior for intelligence, language, spatial cognition, and executive functioning; and low average range for memory. Id. at 62. Mood testing indicated "bewilderment/confusion," which Dr. Flaherty-Craig attributed to "residual declines in attention and concentration in association with persistent disruptions to frontal subcortical mediated aspects of attentional processing." Id. Dr. Flaherty-Craig's impression was that the pattern of findings was consistent with recovering encephalopathy. Id. at 68. Mr. Langley was instructed to return for continued formal assessment to involve formal psychometric evaluation. Id.

On June 15, 2016, Mr. Langley returned to Dr. Flaherty-Craig. Exhibit 15 at 23-24. She noted that Mr. Langley had undergone a formal neuropsychological assessment and that the pattern of findings had been indicative of persistent disruptions of the frontal subcortical mediated aspects of attention processing. Id. at 23. Her impression was that Mr. Langley was presenting with largely resolved encephalopathy evidenced in the formal neuropsychological assessment over the past several months. Id. at 24. Mr. Langley's cognitive capacities had largely

[6] Dr. Khan's report does not mention the tetanus vaccination.

returned to baseline, but he had residual declines of attentional processing and executive functioning. Id. Dr. Flaherty-Craig expected that Mr. Langley would likely continue his current course of slow progressive gains and instructed him to follow-up should he experience a plateau or decline in his cognitive behavioral status. Id.

Mr. Langley appealed the cessation of disability benefits. Exhibit 54-2 at 559-62 [pdf 88] (Sep. 6, 2016).

On September 30, 2016, Mr. Langley returned to Dr. Flaherty-Craig for continued formal neuropsychological assessment. Exhibit 15 at 4. Dr. Flaherty-Craig's impression was that Mr. Langley remained in the chronic course of recovery from apparent adverse reactions to rabies and tetanus vaccinations. Id. at 5. Mr. Langley continued to exhibit residual difficulties for aspects of higher-level language processing and executive regulation of problem solving. Id. Mr. Langley was instructed to return for completion of the Guilford Social Intelligence Battery as well as continued remediation planning. Id. at 6.

A representative of the insurance company providing disability benefits to Mr. Langley requested that a doctor review information related to Mr. Langley's "functional impairments, restrictions and limitations if any from 1/16/15-PRESENT." Exhibit 54-2 at 531 (assignment date October 26, 2016). The doctor who performed this review was Lee Hartner, who identifies himself as board certified in internal medicine, hospice and palliative medicine, hematology, and medical oncology. Id. at 532-33. Dr. Hartner summarized a long list of medical records. Dr. Hartner also stated that he attempted to speak with Dr. Williams, but Dr. Williams did not return his call. Based upon the documents Dr. Hartner reviewed, Dr. Hartner opined that Mr. Langley "has had various somatic symptoms but no actual abnormality has been diagnosed by the treating providers." Id. at 532. Dr. Hartner noted that Mr. Langley "was following with a hematologist but had not actually been diagnosed with any hematologic condition." Id. With respect to the neuropsychological testing that "revealed some abnormalities," "any assessment of restrictions or limitations due to that or psychiatric conditions is beyond the scope of this review." Id.

The insurance company's representative also sought a review from a psychologist, Jeremy Hertza. Like Dr. Hartner, Dr. Hertza reviewed a lengthy set of medical records. Also, like Dr. Hartner, Dr. Hertza attempted to reach his peer, Dr. Flaherty-Craig, but received no response. Exhibit 54-2 at 541. Dr. Hertza stated that Mr. Langley has "indications of mildly variable attention, but otherwise, there is no evidence of functional deficit that would correspond to the claimant[']s

report, regard[less] of SPECT results." Id. at 542. Dr. Hertza concluded "the medical record does not support severe functional impairment for the time in question, from a psychological perspective." Id.

In response to Dr. Hartner's letter, Dr. Williams wrote another letter on Mr. Langley's behalf. Dr. Williams opined that Mr. Langley clearly fulfilled the criteria for Post-Vaccination Encephalomyelitis with prolonged symptoms. Exhibit 18 at 220 (November 30, 2016). He based his opinion on Mr. Langley's SPECT and MRI images. Id. Dr. Williams further opined that Mr. Langley was unable to perform any of the functions required by his job as a result of his condition. Id.

Dr. Williams's November 30, 2016 letter did not change how Dr. Hartner or Dr. Hertza assessed Mr. Langley's condition. See exhibit 54-2 at 731-35 [pdf 260], exhibit 54-4 at 1534-35 [pdf 14-15]; 1541-42; see also exhibit 54-2 at 1035 [pdf 564].

In the context of Mr. Langley's claim for disability benefits, a neurologist whom Mr. Langley did not retain, Amy Sanders, reviewed Mr. Langley's medical records. Dr. Sanders noted the "record consistently documents subjective complaints [that] present in a manner that is disproportionate to any objective findings." Exhibit 54 at 621. Furthermore, it was noted that "anxiety and stress-related reactions were favored as the etiology of claimant's presentation by Drs. Uniacke [PCP], Tkatch, and Baker." Id. Under conclusions, Dr. Sanders wrote she is "convinced by Dr. Flaherty-Craig's arguments that claimant will be unable to perform his prior occupation." Id. at 623.

The insurance company terminated Mr. Langley's long-term benefits pursuant to an August 17, 2017 letter. Exhibit 54-3 at 1220. With the assistance of an attorney, Mr. Langley appealed that termination. Exhibit 54-2 at 833 [pdf 362].

On October 12, 2017, Mr. Langley presented to Dr. Annibali to review the results of his recent SPECT study. Exhibit 19 at 1. Dr. Annibali explained that the results continued to suggest a brain injury and/or temporal lobe atrophy. Id. Dr. Annibali commented "[u]nfortunately, we have not yet identified the nature of his initial brain injury." Id.

Although Mr. Langley has filed more recent medical records, both parties' summaries of relevant facts end with the visit to Dr. Annibali on October 12, 2017. See Pet'r's Br. at 9; Resp't's Br. at 7. Further, the parties stated in the October 1, 2021 status conference that the medical records created after this date do not affect

whether Mr. Langley can establish with preponderant evidence whether the vaccination harmed him. Accordingly, these additional medical records are not summarized here.[7]

II. Procedural History

Mr. Langley initiated this action by filing a petition on June 21, 2017. Over the next few months, he periodically filed medical records, and, on October 18, 2017, Mr. Langley represented that the record was substantially complete.

The Secretary reviewed this material and recommended that compensation be denied. Resp't's Rep., filed pursuant to Vaccine Rule 4 on February 26, 2018. The Secretary argued that Mr. Langley did not satisfy the requirements for an on-Table claim based upon the pertussis component of the Tdap vaccine because Mr. Langley did not establish that he suffered an encephalopathy within 72 hours of administration of the vaccine. Id. at 20. For the alternative means of entitlement, the Secretary contended that Mr. Langley had not met the prongs from Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Id. at 21-23.

During the ensuing status conference, Mr. Langley expressed an intention to obtain a report from an expert. To facilitate the process of presenting adequate reports from experts, the undersigned proposed a set of draft instructions. Order, issued March 6, 2018. When neither party commented on the proposed instructions, they became final. Order, issued March 22, 2018.

The Instructions directed any expert whom Mr. Langley retained to explain any relevant condition that a vaccine may have caused. "The expert should describe whether Mr. Langley suffered an 'acute encephalopathy' or another form of encephalopathy, including the diagnostic criteria." Instructions, issued March 22, 2018, ¶ 4.b. "The expert should identify the evidence supporting (or not supporting), the opinion that Mr. Langley suffered (or did not suffer) an encephalopathic event. In presenting their opinions about diagnosis, the experts must cite underlying medical records by exhibit number and page number." Id. at ¶ 4.d.

[7] On December 6, 2017, the Social Security Administration determined that Mr. Langley was entitled to monthly disability benefits beginning July 2015. Exhibit 54 at 602 [pdf 131]; see also exhibit 54-2 at 922 [pdf 451]. By April 2018, the insurance company reinstated Mr. Langley's long-term disability benefits. Id. at 821 [pdf 350]; exhibit 54-3 at 1260.

Mr. Langley submitted a report from Dr. Lawrence Steinman on October 17, 2018. Dr. Steinman opined that Mr. Langley suffered from an encephalopathy as well as "generalized anxiety disorder." Exhibit 26 at 17. However, the relationship between these two conditions was not clear and Mr. Langley was ordered to obtain another report from Dr. Steinman. This supplemental report was filed on December 3, 2018. Exhibit 28.

The Secretary's response to Dr. Steinman's opinions was twofold. First, the Secretary submitted a report from Elizabeth LaRusso, a psychiatrist. Dr. LaRusso stated that Mr. Langley suffered from "an adjustment disorder with depressed mood lasting from approximately August to November of 2014." Exhibit A at 12. She disagreed with Dr. Steinman's suggestion of generalized anxiety disorder. Id. at 11.

The second expert whom the Secretary retained is Robert Naismith, a neurologist. Dr. Naismith disagreed with Dr. Steinman's opinion that Mr. Langley suffered from an encephalopathy. Exhibit I at 16-17.

Because the Secretary presented an opinion from a psychiatrist, Dr. LaRusso, Mr. Langley also presented a report from a psychiatrist, Tracey Marks. Exhibit 30. Dr. Marks opined that an appropriate diagnosis for Mr. Langley is "an acute adjustment disorder with mixed anxiety and depressed mood that developed after Mr. Langley received the two vaccines on July 31, 2014 . . . . His adjustment disorder resolved as of November 2014." Id. at 10. Dr. Marks mentions Dr. Steinman's proposed diagnosis of generalized anxiety disorder only in passing. Id. at 15. Dr. Marks also opines that Mr. Langley "later developed an encephalopathy." Id. at 10. Although Dr. Marks mentions encephalopathy, she "defer[red] to the neurology experts to discuss this disorder." Id. at 11.

When Mr. Langley submitted the report from Dr. Marks, he was aware of the report from Dr. Naismith. However, Mr. Langley did not submit a reply from Dr. Steinman.

The Secretary obtained another report from Dr. LaRusso. This report notes that Dr. LaRusso and Dr. Marks agree that Mr. Langley suffered an adjustment disorder with mixed anxiety and depressed mood lasting from August to November 2014. But, they disagree as to the cause. Exhibit FF.

Dr. LaRusso's report appeared to complete the written submissions from experts. Accordingly, the parties were directed to file briefs in advance of a potential adjudication. Order, issued April 24, 2020. This order established

procedures that are important in at least three respects. First, the order alerted the parties that the case might be decided without any oral testimony. Id. at 1. Second, this order instructed Mr. Langley to obtain more information, including his employment file and documents associated with his claims for disability benefits. Id. at 1-2. Third, this order reviewed the different diagnoses that the experts had proposed. The order stated, "Mr. Langley must define the condition (or conditions) that he alleges the vaccination caused in him." Id. at 5. Due to the complexity of the issue, the undersigned expected that "the section on diagnosis may be four or more pages." Id. at 6.

Mr. Langley submitted additional information. Exhibits 32-55. Due to the volume of additional information, especially with respect to the claim for long-term disability benefits, the parties were given an opportunity to have their experts comment on the new evidence. Order, issued September 21, 2020.

Around this time, Mr. Langley's former counsel of record ceased her representation of him. Ms. McCullough became counsel of record on November 30, 2020.

In response to the September 21, 2020 order for additional expert reports, Mr. Langley filed another report from Dr. Marks on December 17, 2020. Exhibit 56. Mr. Langley also sought additional time to file a report from Dr. Steinman. Pet'r's Mot., filed Dec. 21, 2020.

A status conference was held on January 22, 2021. In this status conference, Ms. McCullough represented that Dr. Steinman did not have more information to add. The undersigned advised Ms. McCullough, who was new to the case, that Mr. Langley's claim had not been persuasively explained to date. Thus, the undersigned encouraged Ms. McCullough to assess whether the claim should be pursued further. Order, issued Jan. 22, 2021. Mr. Langley wished to press forward. Pet'r's Status Rep., filed Feb. 22, 2021.

In accord with the April 24, 2020 order for briefs, Mr. Langley submitted his primary memorandum on May 20, 2021. He argued "Petitioner suffered from encephalopathy as a result of receiving the TDaP vaccination on August 1, 2014." Pet'r's Br. at 10. Mr. Langley cited records from Dr. Annibali, Dr. Williams, Dr. Flaherty-Craig, and reports from Dr. Steinman and Dr. Marks. The analysis is approximately two pages. Id. at 10-12. In this section of the brief, Mr. Langley

did not assert that the vaccination caused either a generalized anxiety disorder or an acute adjustment disorder.[8]

Just as Mr. Langley had an opportunity to have his experts review exhibits 32-55, the Secretary had the same chance. The Secretary presented supplemental reports from Dr. LaRusso and Dr. Naismith on July 26, 2021. Exhibits GG-HH. The Secretary next submitted his brief on September 16, 2021. The Secretary argued against the diagnosis of encephalopathy over the course of approximately three pages. Resp't's Br. at 18-22.

Neither Mr. Langley nor the Secretary complied with all the requirements of the April 24, 2020 order for briefs. These potential problems were discussed in a digitally recorded status conference held on October 1, 2021. Based upon discussions in that status conference, Mr. Langley was scheduled to file a reply brief and the Secretary was permitted to file a supplemental statement.

Mr. Langley replied to the Secretary's arguments in a brief submitted on November 10, 2021. Mr. Langley argued he "developed an encephalopathy when . . . the TDaP vaccination induced . . . cytokines, and . . . Petitioner's encephalopathy triggered an acute adjustment disorder with mixed anxiety." Pet'r's Reply at 3.

The Secretary filed his remaining pre-adjudication materials on December 1, 2021. With the submission of that material, Mr. Langley's case is ready for adjudication.

III. Standards for Adjudication

Petitioners are required to establish their cases by a preponderance of the evidence. 42 U.S.C. § 300aa–13(1)(a). The preponderance of the evidence standard requires a "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." Moberly v. Sec'y of

[8] At best, Mr. Langley identifies Dr. Marks as presenting an opinion that Mr. Langley suffered "an acute adjustment disorder with mixed anxiety and depressed mood that developed after Petitioner's vaccine-induced encephalopathy." Pet'r's Br. at 12. But Mr. Langley does not develop any argument regarding "an acute adjustment disorder" as he goes on to argue that "In support of Petitioner's claim that the TDaP vaccination caused Petitioner's encephalopathy, Petitioner has submitted reports from Dr. Lawrence Steinman." Id. at 12.

Health & Hum. Servs., 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted).

The process for finding facts in the Vaccine Program begins with analyzing the medical records, which are required to be filed with the petition. 42 U.S.C. § 300aa–11(c)(2). Medical records that are created contemporaneously with the events they describe are presumed to be accurate. Cucuras v. Sec'y of Health & Hum. Servs., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

IV. Analysis

Mr. Langley's claim for compensation fails for two independent reasons. First, as discussed in section A below, he has not established that he suffered from an encephalopathy, which is the condition he claims the tetanus vaccine caused. The failure of proof on that point is dispositive. Second, even if the record supported finding that encephalopathy is an appropriate diagnosis for Mr. Langley, he has not presented persuasive proof to establish the tetanus vaccine caused his hypothetical encephalopathy.

A. Diagnosis

As a threshold matter, a petitioner must establish he suffers from the condition for which he seeks compensation. Broekelschen v. Sec'y of Health & Hum. Servs., 618 F.3d 1339, 1346 (Fed. Cir. 2010). When a petitioner fails to establish his diagnosis, there is no need for an analysis pursuant to Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Lombardi v. Sec'y of Health & Hum. Servs., 656 F.3d 1343, 1353 (Fed. Cir. 2011).

The process for determining whether a vaccinee suffers from a particular disease begins by setting forth the criteria by which doctors define the condition. Then, the evidence about the vaccinee is reviewed to see whether preponderant evidence favors a finding that the vaccinee suffered from a particular condition.

1. Diagnostic Criteria

The parties differ, to a degree, about the criteria for diagnosing an encephalopathy. Mr. Langley emphasizes the *functional* aspects. He argues, "As defined by the National Institute of Neurological Disorders and Stroke, encephalopathy is a term for any diffuse disease of the brain that alters the brain

function or structure." Pet'r's Br. at 10, citing exhibit 27.7.[9] Relying upon this same source, Mr. Langley states that in an encephalopathy, "common neurological symptoms are progressive loss of memory and cognitive ability, subtle personality changes, inability to concentrate, lethargy, and progressive loss of consciousness." Id. at 10-11.

By way of (slight) contrast, the Secretary emphasizes the *organic* nature of encephalopathy. Citing the report from his expert, Dr. Naismith, the Secretary maintains, "[e]ncephalopathy is a general term for a structural or metabolic abnormality, which results in cognitive dysfunction." Resp't's Br. at 19, citing exhibit I (Dr. Naismith's report) at 2. The Secretary further argues that "[e]ncephalopathy is often associated with abnormalities on an EEG, blood tests, spinal fluid examination, imaging studies, electroencephalograms, and similar diagnostic studies." Id. at 20, citing exhibit I at 2 and exhibit 26 (Dr. Steinman's report) at 18. The Secretary asserts that "[e]ncephalopathy is diagnosed by a decreased or absent response to the environment (arousal), decreased or absent eye contact (attention), inconsistent or absent response to external stimuli, and a seizure with loss of consciousness." Id., citing exhibit I at 2.

Other special masters have discussed definitions of "encephalopathy" in the context of non-Table claims. Although less strictly defined than a Table encephalopathy, a non-Table encephalopathy is not so expansive as to include any possible brain injury. See Prokopeas v. Sec'y of Health & Hum. Servs., 04-1717V, 2019 WL 2509626, at *18 (Fed. Cl. Spec. Mstr. May 24, 2019). Reliable evidence in the record is required to establish that an injured party's symptoms constitute an encephalopathy. Some special masters have identified specific symptoms suggestive of an encephalopathy. See Cook v. Sec'y of Health & Hum. Servs., No. 00-331V, 2005 WL 2659086, at *14 (Fed. Cl. Spec. Mstr. Sept. 21, 2005) (discussing an acute non-Table encephalopathy as capable of manifesting symptoms such as "crying, anorexia, insomnia, fever, moodiness, irritability, depression, . . . "); Noel v. Sec'y of Health & Hum. Servs., No. 99-538V, 2004 WL 3049764, at *17 (Fed. Cl. Spec. Mstr. Dec. 14, 2004) (finding petitioner suffered an acute transient encephalopathy "with symptoms of moaning, high-pitched and eerie crying, and unresponsiveness").

[9] Petitioner's citation is a webpage screenshot of the National Institute of Health's "Encephalopathy Information Page," dated Oct. 17, 2018.

2. Evidence regarding Mr. Langley

Here, evidence regarding Mr. Langley can be divided into three groups. These are (a) tests performed by his treating medical personnel, (b) reports created by medical personnel during their course of treating Mr. Langley, and (c) reports created by experts whom the parties retained in this litigation. These are considered in turn.

a) Tests Administered to Mr. Langley

As noted above, the Secretary's diagnostic criteria for encephalopathy included the results of various tests, including an electroencephalogram, spinal fluid examination, and "imaging studies." Resp't's Br. at 19. In reply, Mr. Langley did not challenge these factors as contributing to the process for determining whether an encephalopathy is an appropriate diagnosis. See Pet'r's Reply.

The Secretary evaluated Mr. Langley's condition by these factors, at least in part. The Secretary argued Mr. Langley "underwent a neurological exam, spinal fluid exam, EEG, EMG, and three MRI scans, which were all within normal limits." Resp't's Br. at 20-21, citing exhibit 11 at 39; exhibit 12 at 4, 10, 14; exhibit 16 at 7; exhibit 15 at 104, 115; exhibit 18 at 18-20.[10] The Secretary also argued that the neuropsychological testing from 2016 "did not show a consistent pattern of abnormalities on cognitive testing." Resp't's Br. at 20, citing exhibit 15 at 52-62. The Secretary maintained that "there are no medical records that indicate that petitioner suffered a seizure with a loss of consciousness." Id. Based upon this review of information, the Secretary concluded, "Thus, the diagnostic testing does not support an inflammatory reaction within the central nervous system or a diagnosis of encephalopathy." Id. at 21.

Mr. Langley did not controvert the Secretary's assertions, leaving them unchallenged. See Pet'r's Reply at 3-4. This lack of response opens questions as to how Mr. Langley can present preponderant evidence that he suffered an encephalopathy in light of consistent testing that did not show an encephalopathy. The answer is that Mr. Langley relies upon reports from some of the doctors who treated him.

[10] An independent review confirms that the exhibits cited in respondent's brief support the Secretary's assertions.

b) Reports Created by Medical Personnel during their Treatment

Congress directed special masters to consider "any diagnosis . . . which is contained in the record regarding the nature . . . of the petitioner's illness, disability, injury, [or] condition." 42 U.S.C. § 300aa–13(b). However, "Any such diagnosis . . . shall not be binding on the special master." Id.

The opinions of treating doctors can be quite probative. Cappizano v. Sec'y of Health & Hum. Servs., 440 F.3d 1317, 1326 (Fed. Cir. 2006). The views of treating doctors about the appropriate diagnosis are often persuasive because the doctors have direct experience with the patient whom they are diagnosing. See McCulloch v. Sec'y of Health & Hum. Servs., No. 09-293V, 2015 WL 3640610, at *20 (Fed. Cl. Spec. Mstr. May 22, 2015). However, the views of a treating doctor are not absolute, Snyder v. Sec'y of Health & Hum. Servs., 88 Fed. Cl. 706, 745 n.67 (2009), even on the question of diagnosis, R.V. v. Sec'y of Health & Hum. Servs., 127 Fed. Cl. 136, 141 (2016), appeal dismissed, No. 16-2400 (Fed. Cir. Oct. 26. 2016).

Here, Mr. Langley was evaluated by different doctors after receiving the vaccinations on August 1, 2014. This chronological list begins with Dr. Uniacke.

Following the August 1, 2014 vaccinations, the first doctor whom Mr. Langley saw was Dr. Uniacke on August 21, 2014. Mr. Langley complained about feeling anxious and having headaches. Exhibit 11 at 48. Dr. Uniacke's history is relatively detailed, noting that Mr. Langley's anxiety "began 2-3 weeks ago shortly after he had received immunoglobulin and [an] initial rabies vaccine." Id.[11] Dr. Uniacke memorialized that Mr. Langley has "had several personal stressors including the unexpected death of an Aunt." Id. In Dr. Uniacke's physical examination, she determined that Mr. Langley's level of consciousness was "normal," he was oriented to "time, place, person & situation," and he had an "[a]ppropriate mood and affect." Id. at 51. Under "psychiatric," Dr. Uniacke described Mr. Langley as having "[a]nhedonia" and being "anxious." Id. Dr. Uniacke assessed Mr. Langley as suffering from common migraines and an "[a]djustment disorder with mixed anxiety and depressed mood." She stated that Mr. Langley could take lorazepam for acute anxiety or panic attacks. Id. Dr. Uniacke did not diagnose Mr. Langley as suffering from an encephalopathy.

[11] This history does not mention a tetanus or Tdap vaccine.

Nine days later, due to Mr. Langley's concern about cognitive issues and memory problems, he sought treatment at an emergency room. The doctor assessed Mr. Langley as suffering from cognitive changes and recommended that he follow up with a neurologist. Exhibit 13 at 9-12. This doctor also did not diagnose Mr. Langley as suffering from an encephalopathy.

Mr. Langley's neurologist was Dr. Liana Laza. In the September 16, 2014 appointment, Dr. Laza diagnosed Mr. Langley as having "superimposed anxiety." Exhibit 12 at 11.

A fourth doctor whom Mr. Langley saw within about two months of the vaccinations was a specialist in infectious diseases, Lisa Tkatch. Dr. Tkatch indicated that Mr. Langley was possibly suffering from a "post traumatic stress reaction". Exhibit 16 at 7. Dr. Tkatch did not diagnose Mr. Langley as suffering from an encephalopathy.

Around the time Mr. Langley was seeing Dr. Laza and Dr. Tkatch, he had follow up appointments with Dr. Uniacke. Exhibit 11 at 44-46 (Sept. 5, 2014), 41-43 (Sept. 19, 2014), 38-41 (Oct. 10, 2014), and 33-37 (Nov. 13, 2014). In these appointments, Dr. Uniacke did not diagnose Mr. Langley as suffering from encephalopathy.

In arguing that he suffered from an encephalopathy, Mr. Langley did not address the treatment records of these doctors. For example, he did not present any argument about how these doctors could have missed diagnosing him with an encephalopathy. Instead, Mr. Langley's contention begins with Dr. Annibali and Dr. Williams. See Pet'r's Br. at 6-9, 16-17; Pet'r's Reply at 3-4.

Mr. Langley saw Dr. Williams before he saw Dr. Annibali. In the first appointment with Dr. Williams, Mr. Langley complained about "delirium and confusion." Exhibit 18 at 14. Based in part on the MRI and in part on the history from Mr. Langley, Dr. Williams found that Mr. Langley suffered from a "central . . . neuropathy." Id. at 15. Dr. Williams also supported Mr. Langley's claim for disability benefits. Id.

Additional information to support Mr. Langley's claim came from Dr. Annibali, whom Mr. Langley saw on January 13, 2015. Dr. Annibali administered a SPECT scan and diagnosed Mr. Langley with an encephalopathy, based, at least in part, on the results of the SPECT scan. Exhibit 2 at 10.

Dr. Williams, in turn, incorporated some of Dr. Annibali's opinions when next supporting Mr. Langley's claim for disability benefits. Dr. Williams stated

that given Mr. Langley's diagnosis of encephalopathy, he could not perform the functions of his job. Exhibit 4 (Feb. 2, 2015).

In addition to Dr. Williams and Dr. Annibali, Mr. Langley also relies upon a neuropsychologist, Claire Flaherty-Craig. Pet'r's Br. at 12, citing exhibit 15 at 68. The report that Mr. Langley cites is the report from Mr. Langley's first visit with Dr. Flaherty-Craig on April 6, 2016, after a referral by Dr. Williams. In that appointment, Mr. Langley gave a history of his illness. Dr. Flaherty-Craig also mentioned that she reviewed some documents from people who treated Mr. Langley including Dr. Tkatch. Dr. Flaherty-Craig does not mention any documents from Dr. Uniacke. Based upon this information, Dr. Flaherty-Craig's impression was that Mr. Langley's presentation was "consistent with recovering encephalopathy." Exhibit 15 at 68.

After this appointment, Mr. Langley returned for "formal neuropsychological assessment" on April 29, 2016. Id. at 56. Mr. Langley took multiple tests. Overall, his scores were in the "average range." Id. at 62.

Another round of testing took place on May 4, 2016. Exhibit 15 at 44. "In the domain of memory, Mr. Langley's scores ranged from very superior to average. On measures of attention and executive functioning, his scores were in the superior to low average range." Id. at 52. Dr. Flaherty-Craig concluded Mr. Langley's "pattern of findings remains consistent with residual declines in attention/concentration and verbal abstract reasoning in association with persistent disruptions to frontal subcortical mediated aspects of attentional processing and verbal problems solving." Id.

Dr. Flaherty-Craig reviewed the results with Mr. Langley and his wife on June 16, 2016. Dr. Flaherty-Craig stated he "presents with largely resolved encephalopathy, evidenced in formal neuropsychological assessment over the past several months. His cognitive capacities have largely returned to his apparent superior range baseline . . . . He does remain with a number of average range findings, which likely represent residual declines for aspects of attentional processing and executive functioning. These will likely continue to resolve in the months ahead." Exhibit 15 at 24.

c) Reports created by Doctors Retained in this Litigation

The third type of evidence relevant to determining whether Mr. Langley suffered an encephalopathy is the set of reports prepared by doctors whom the parties retained to offer opinions. See 42 U.S.C. § 300aa–13(a) (authorizing

special master to make decisions based upon "medical records or medical opinions").

In this case, Mr. Langley advances opinions from Dr. Steinman and Dr. Marks. Pet'r's Br. at 12. In Dr. Steinman's report, Dr. Steinman stated that Mr. Langley suffered from an encephalopathy. Exhibit 26 at 17-18, 24. However, the Secretary's expert, Dr. Naismith, opined that Mr. Langley's "medical records do not support a diagnosis of encephalopathy." Exhibit I at 2.

In response to Dr. Naismith, Mr. Langley did not obtain a supplemental report from Dr. Steinman. Instead, Mr. Langley submitted a report from Dr. Marks, who also responded to a report from the Secretary's other expert, Dr. LaRusso. Dr. Marks stated, "the medical records support a diagnosis of an acute adjustment disorder with mixed anxiety and depressed mood that developed after Mr. Langley received the two vaccines on July 31, 2014 and later developed an encephalopathy." Exhibit 30 at 10. Dr. Marks focuses her analysis on the "adjustment disorder" because she deferred to neurology experts to discuss encephalopathy. Id. at 11.[12]

d) Evaluation

Considered as a whole, the record does not support finding, on a more likely than not basis, that Mr. Langley suffered an encephalopathy. This finding is based upon several factors.

First, as noted above, the various objective tests, such as EEG and MRIs, are not consistent with a finding of encephalopathy. While the Secretary argued this point, Mr. Langley did not explain how negative (or normal) results on objective tests could be consistent with a diagnosis of encephalopathy.

Second, the reports of the treating doctors, considered collectively, do not support a finding of encephalopathy. Within the first four months of the vaccination, Mr. Langley saw four doctors, including a neurologist. Their reports are valuable because they were created relatively close in time to the vaccination. None of these doctors diagnosed him as suffering from an encephalopathy. The lack of diagnosis from four different doctors suggests, but does not absolutely prove, that Mr. Langley was not suffering from an encephalopathy.

[12] Dr. LaRusso, too, deferred to neurologists about "the presence of encephalopathy." Exhibit FF at 1; accord exhibit A at 8.

To be sure, the reports from Dr. Williams and Dr. Annibali provide some support for Mr. Langley's contention. However, the foundation for their opinions is shaky. Dr. Annibali appears heavily influenced by the result of the SPECT scan. See exhibit 2 at 9; see also Pet'r's Br. at 11 (stating that Dr. Annibali's diagnosis of encephalopathy "came after review of SPECT imaging"). But, Dr. Naismith and Dr. LaRusso stated that SPECT imaging is not useful for diagnosing encephalopathy. Exhibit A at 10, citing guidance from the American Psychiatric Association; exhibit I at 16. On this point, Dr. Marks agreed. Exhibit 30 at 16 ("Mr. Langley's evaluation with Dr. Annibali and his subsequent recommendations would be considered alternative medicine"). Similarly, in other cases, credentialed experts have testified that SPECT scans are not accepted by the American Academy of Neurology for diagnosing encephalopathy except for with AIDS patients. See, e.g., Falksen v. Sec'y of Health & Hum. Servs., 01-317V, 2014 WL 785056, at *11 (Fed. Cl. Spec. Mstr. Mar. 30, 2004). Thus, Dr. Annibali's opinion carries less weight.

This same flaw—reliance on the SPECT study—also undermines Dr. Williams's later opinions. Dr. Williams's first opinion was that Mr. Langley suffered from a central neuropathy, a term that could be consistent with an encephalopathy. However, this opinion was based upon Dr. Williams's interpretation of the September 19, 2014 MRI. Exhibit 18 at 14. Dr. William's interpretation seems inconsistent with the opinion Dr. Laza reached. See exhibit 12 at 7 (report from Oct. 28, 2014). Because Dr. Laza is a neurologist and Dr. Williams is a hematologist/oncologist, Dr. Laza is better qualified to understand the significance of an MRI. See exhibit 26 (Dr. Steinman's report) at 17 (discussing qualifications of neurologists).

The final treating doctor who considered Mr. Langley to have suffered an encephalopathy is Dr. Flaherty-Craig. Dr. Flaherty-Craig's assessment carries relatively less weight because she offered opinions starting in April 2016, approximately 20 months after the vaccination. See Holt v. Sec'y of Health & Hum. Servs., 132 Fed. Cl. 194, 199-201 (2017) (denying motion for review and ruling that the special master was not required to defer to opinions of doctors who began treating the vaccinee years after the vaccination); Nuttal v. Sec'y of Health & Hum. Servs., 122 Fed. Cl. 821, 833-34 (2015) (denying motion for review and ruling that special master was not arbitrary or capricious in declining to credit opinion of a doctor who began treating the vaccinee years after the vaccination), aff'd without op., 2015-5153, 640 Fed. Appx. 996 (Fed. Cir. May 17, 2016); Goforth v. Sec'y of Health & Hum. Servs., No. 14-1128V, 2021 WL 6337672, at *29 (Fed. Cl. Spec. Mstr. Nov. 19, 2021) (declining to credit a treating doctor who

started seeing vaccinee nearly four years after vaccination); Martin v. Sec'y of Health & Hum. Servs., No. 13-486V, 2020 WL 6865931, at *44-45 (Fed. Cl. Spec. Mstr. Oct. 27. 2020) (declining to credit views of treating doctor who began treating vaccinee one year after vaccination and who did not review medical records). Her neuropsychological testing revealed that Mr. Langley usually scored in the average or above-average range. Exhibit 15 at 47, 62.

Dr. Flaherty-Craig opined that while Mr. Langley had mostly returned to his baseline, Dr. Flaherty-Craig did not explain how she could determine that he ever suffered from an encephalopathy. As Dr. LaRusso explained, "in the absence of baseline data prior to the alleged injury, . . . it is difficult to assess whether this was a change from Mr. Langley's baseline." Exhibit A at 8.

Third, the reports of the retained doctors offer little assistance. Dr. Marks, as noted above, deferred to neurologists about the presence of an encephalopathy. Exhibit 30 at 11. Thus, Mr. Langley's case finally turns on the opinion from Dr. Steinman.

Dr. Steinman does state that Mr. Langley suffered an encephalopathy. Exhibit 26 at 17-18, 24. But, this statement appears to be an unsupported assertion. The Secretary argued that "Dr. Steinman never actually explained what testing and studies he used to determine that petitioner actually had encephalopathy." Resp't's Br. at 19. Mr. Langley did not clarify the basis for Dr. Steinman's opinion. See Pet'r's Reply at 3-4. This lack of development reduces the value of Dr. Steinman's opinion. See Duncan v. Sec'y of Health & Hum. Servs., 153 Fed. Cl. 642, 661 (2021) (denying motion for review and finding that the special master was not arbitrary in observing that the reports from petitioner's experts were conclusory); Harrington v. Sec'y of Health & Hum. Servs., 139 Fed. Cl. 465, 470 (2018) (denying motion for review and indicating that there was no basis to disturb the special master's description of petitioner's expert opinion as "unpersuasive, conclusory, and disjointed").

In contrast to Dr. Steinman, Dr. Naismith provided specific reasons why he (Dr. Naismith) found that Mr. Langley did not suffer from an encephalopathy. These reasons included the lack of confirmation through various objective tests, which returns the analysis full circle. See exhibit I at 16-17. Thus, between the two retained neurologists, Dr. Naismith is more persuasive than Dr. Steinman.

B. Causation-in-Fact

While a finding that Mr. Langley does not suffer from an encephalopathy resolves this case, additional elements of his claim will be discussed for sake of completeness under the assumption that Mr. Langley had presented preponderant evidence that he suffered an encephalopathy. Because the Vaccine Injury Table does not associate encephalopathy with a tetanus vaccine, Mr. Langley must establish that the vaccine caused his encephalopathy.

To establish causation for off-Table injuries, petitioners bear a burden "to show by preponderant evidence that the vaccination brought about [the vaccinee's] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

1. Medical Theory

To supply a medical theory, Mr. Langley relies upon the report from Dr. Steinman. Pet'r's Br. at 12-13; Pet'r's Reply at 1-2. Dr. Steinman asserts that the Tdap vaccine triggered a production of a cytokine (interleukin-1beta) leading to an anxiety disorder. Exhibit 26 at 23. In his second report, Dr. Steinman linked anxiety disorders to encephalopathy. Exhibit 28 at 1-3. To buttress Dr. Steinman's theory, Mr. Langley cites a single article by Bhojani, exhibit 27.10.[13]

In response, the Secretary advances the criticisms made by Dr. Naismith of Dr. Steinman's opinions. Resp't's Br. at 22-24.[14] "As noted by Dr. Naismith, an inflammatory reaction with IL1 might be expected to cause some relatively mild muscle soreness, fever, chills, and fatigue for up to a couple days. A post-vaccination, IL1-mediated inflammatory reaction would not cause a reaction that persisted for years." Id. at 23, citing exhibit I (Dr. Naismith's report) at 19.

---

[13] Shabnamzehra Bhojani et al., *Psychotic Disorder after Contact with a Potentially Rabid Animal and Post-Exposure Prophylactic Anti-Rabies Treatment*, 8 CLINICAL SCHIZOPHRENIA & RELATED PSYCHOSES 149 (2012).

[14] The Secretary accurately states that Dr. Naismith said that the Institute of Medicine discussed whether a Tdap vaccine can cause an encephalopathy. Resp't's Br. at 23, citing exhibit I (Dr. Naismith's report) at 19. However, the Secretary did not file the relevant portions of the IOM report. Therefore, this aspect of Dr. Naismith's argument is disregarded.

Special masters have refrained from crediting the theory that vaccines can cause an illness simply because the vaccines cause transient increases in cytokines. See O.M.V. v. Sec'y of Health & Hum. Servs., No. 16-1505V, 2021 WL 3183719, at *44-46 (Fed. Cl. Spec. Mstr. June 16, 2021), mot. for rev. denied, __Fed.Cl. __, 2021 WL 6124731 (Dec. 8, 2021); Castaneda v. Sec'y of Health & Hum. Servs., No. 15-1066V, 2020 WL 3833076, at *23-27 (Fed. Cl. Spec. Mstr. May 18, 2020), mot. for rev. denied, 152 Fed. Cl. 576 (2020); Martin v. Sec'y of Health & Hum. Servs., No. 15-789V, 2020 WL 4197748, at * 26-28 (Fed. Cl. Spec. Mstr. May 8, 2020), mot. for rev. denied, slip op. (Fed. Cl. Aug. 20, 2020). For similar reasons, Dr. Steinman's cytokine-based theory is not sufficiently supported to be persuasive.

The one article Mr. Langley cites in his primary brief, Bhojani, does not add any meaningful weight to Dr. Steinman's theory. Bhojani and colleagues present a report in which a 19-year-old woman was bitten by a stray dog, given two doses of a rabies vaccine, and then started acting strangely in a way that was consistent with an encephalopathy. Exhibit 27.10 at 1. Although Mr. Langley received a rabies vaccine, his claim in the Vaccine Program rests on the tetanus vaccine. Thus, the Bhojani article does not support Dr. Steinman's theory.

Accordingly, for these reasons, Mr. Langley does not meet Althen prong 1.

2. Logical Sequence of Cause and Effect

Mr. Langley asserts the following as the logical sequence of cause and effect connecting the vaccination to injury. Mr. Langley received a TDaP vaccine, causing him to develop an inflammatory reaction manifesting as encephalopathy (mediated by the aluminum adjuvant) and the encephalopathy caused the development of a mild neurocognitive disorder and reactive anxiety disorder. In support, Mr. Langley cites to several statements from treating physicians. See Pet'r's Br. at 14-15. However, for the reasons that follow, the support provided does not preponderate in petitioner's favor.

A recurring problem with the statements from the treating physicians is that they reference multiple vaccinations and do not attribute any injuries solely to the tetanus vaccine. The first support offered is a statement by Dr. Williams in the medical records. Dr. Williams opined that Mr. Langley's "multiple concurrent vaccinations clearly contributed to the onset of his disability." Exhibit 18 at 15. Mr. Langley next referenced the disability letter Dr. Williams wrote, which states the "onset of all of these symptoms are temporally related to a bite from a stray kitten and the administration of 6 concurrent vaccinations." Exhibit 4 at 1.

Similarly, the treaters at hyperbaric oxygenation centers wrote "[i]t is believed that he experienced an immune reaction to the vaccination cocktail which caused inflammation and attack on the brain's white matter." Exhibit 17 at 6. Dr. Flaherty-Craig wrote under impressions: "apparent adverse reactions to rabies and tetanus vaccines[.]" Exhibit 15 at 5.

Although these statements from treaters provide some general support, they do not persuasively demonstrate that the tetanus vaccine (as opposed to the rabies vaccine, or some combination) caused the alleged injuries. Furthermore, multiple treaters attribute Mr. Langley's condition to the rabies vaccine, not the tetanus portion of his immunizations. Dr. Laza's assessment was that Mr. Langley's "entire complex of symptoms" were a reaction to the rabies vaccination. Exhibit 12 at 7. Dr. Uniacke recorded "Neurologic side effect from Rabies Vaccine" under past medical histories. Exhibit 11 at 33. These treaters' statements cast doubt on Mr. Langley's claim that the tetanus-containing vaccine caused his condition. As such, Mr. Langley has not satisfied the requirements for Althen prong 2.

3. Proximate Temporal Relationship between Vaccination and Injury

Mr. Langley's expert, Dr. Steinman, proposed the onset of encephalopathy and anxiety began within one week of August 1, 2014 vaccination. Exhibit 26 at 23; exhibit 28 at 5. The evidence on this aspect of Mr. Langley's case is murky and could be further developed. However, it is not presently sufficient to carry his case. Due to the preponderance of evidence on the other Althen prongs, the undersigned is not required to evaluate this aspect of Mr. Langley's claim because even when an injury develops after a vaccination, the vaccination is not necessarily the cause of the injury. See Grant v. Sec'y of Health & Hum. Servs., 956 F.2d 1144, 1150 (Fed. Cir. 1992).

V. A Hearing is Not Required

Special masters possess discretion to decide whether an evidentiary hearing will be held. 42 U.S.C. § 300aa-12(d)(3)(B)(v) (promulgated as Vaccine Rule 8(c) & (d)), which was cited by the Federal Circuit in Kreizenbeck v. Sec'y of Health & Hum. Servs., 945 F.3d 1362, 1365 (Fed. Cir. 2018).

Here, Mr. Langley has enjoyed a full and fair opportunity to present his case. The primary issue that determines the outcome of his case, diagnosis, has been raised multiple times. The Final Expert Instructions informed the parties that the experts needed to discuss the appropriate diagnosis, including whether Mr.

Langley suffered an encephalopathy. See Order, issued Mar. 22, 2018, at ¶ 4. After the Secretary's expert (Dr. Naismith) disagreed with Dr. Steinman's opinion that Mr. Langley suffered an encephalopathy, Mr. Langley could have, but did not, obtain a rebutting statement from Dr. Steinman.

The April 24, 2020 order for briefs highlighted the question of diagnosis as the experts had proposed different ideas. In response, Mr. Langley contended that he "suffered from encephalopathy as a result of receiving the TDaP vaccination on August 1, 2014." Pet'r's Br. at 10. Thus, Mr. Langley's theory of recovery requires the presence of encephalopathy. See Hibbard v. Sec'y of Health & Hum. Servs., 698 F.3d 1355, 1365 (Fed. Cir. 2012) (indicating that the special master did not commit a legal error in deciding whether petitioner suffered from a condition, an autonomic neuropathy, that underpinned her entire case).

However, Mr. Langley failed to establish with preponderant evidence that he suffered an encephalopathy. His arguments were relatively conclusory. See Pet'r's Br. at 10-12. Notably, after the Secretary argued that Dr. Steinman did not set forth the basis by which he determined Mr. Langley suffered an encephalopathy, Mr. Langley did not answer this criticism. See Pet'r's Reply at 3-4.

Accordingly, Mr. Langley has been aware of the issues in his case and has had multiple opportunities to present supporting evidence. Under these circumstances, a hearing is not required.

VI. Conclusion

Mr. Langley has not met his burden of demonstrating that he suffered an encephalopathy. Without this showing, he cannot receive compensation. In addition, Mr. Langley's attempt to show that a tetanus vaccine was the cause-in-fact of any encephalopathy was not persuasive. Accordingly, the Clerk's Office is instructed to enter judgment in accord with this decision unless a motion for review is filed. Information about filing a motion for review, including the deadline, can be found in the Vaccine Rules, available through the Court's website.

IT IS SO ORDERED.

s/Christian J. Moran
Christian J. Moran
Special Master